Docket: 2799 (203-3177 PCT US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT(S):	Russell Heinrich et al.	EXAMINER:	Darwin P. Erezo
SERIAL NO.:	10/510,869	ART UNIT:	3773
FILED:	October 7, 2004	DATED:	July 10, 2009
TITLE:	METHOD AND APPARATUS FOR ANASTOMOSIS INCLUDING AN EXPANDABLE ANCHOR		

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BRIEF ON APPEAL

Sir:

This is an appeal from a Final Office Action mailed on December 2, 2008 and an Advisory Action mailed on February 24, 2009 in the above-identified application. This Brief is accompanied by the requisite fees set forth in 37 C.F.R. §41.20 (b)(2).

I. REAL PARTY IN INTEREST

The real party in interest for this application is Tyco Healthcare Group LP (d/b/a Covidien), having a principal office at 60 Middletown Avenue, North Haven, CT 06473.

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being transmitted on the date below with the United States Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450, via electronic submission.

Dated: July 10, 2009

Nicole Rispone

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and/or the assignee of Appellants' interest in the above-identified application are not aware of any related appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by or have a bearing on any decision by the Board of Patent Appeals and Interferences in this appeal.

III. STATUS OF CLAIMS

The status of the claims of this application is as follows:

A) Claims 1-10, and 12-44 are pending;

B) Claims 1-10, 12-25, and 44 stand finally rejected and are being appealed;

C) Claim 11 has been cancelled; and

D) Claims 26-43 have been previously withdrawn.

An accurate copy of Claims 1-10, 12-25, and 44 is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

The Advisory Action mailed April 6, 2009 indicates that the Response to the Final Office Action of January 21, 2009, filed on March 19, 2009 (referred to on the Advisory Action under "Request for Reconsideration/Other") has been considered but failed to place the application in condition for allowance. No amendments have been submitted after Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1 is directed to a device for joining a first body vessel to a second body vessel. (Specification page 11, line 18 – page 12, line 2). The device includes an inner member having a distal end portion and defining a longitudinal axis. (Specification page 12, lines 15-18). An outer member defines a lumen dimensioned to receive the inner member therein. (Specification page 12, lines 12-14). A radially expandable anchor is disposed at the distal end of the inner member. (Specification page 12, lines 8-9). The expandable anchor has an initial condition wherein the expandable anchor is disposed between the outer member and the inner member (Specification page 16, lines 6-8), and the expandable anchor has an expanded condition. (Specification page 12, line 22 – page 13, line 2). A sheath is disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition. (Specification page 21, lines 13-16).

Independent Claim 15 is directed to a device for performing a surgical anastomosis of a first body vessel and a second body vessel. (Specification page 11, line 18 – page 12, line 2). The device includes a pair of concentric tubular sleeves including an outer sleeve and an inner sleeve. (Specification page 12, lines 6-8). Each of the pair of concentric tubular sleeves has a distal end portion and a proximal end portion. (Specification page 12, lines 10-14). A radially expandable anchor is operatively disposable between the distal end portions of the pair of concentric tubular sleeves. (Specification page 14, line 21 – page 15, line 4). The radially

expandable anchor includes a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels. (Specification page 17, lines 18-20). The radially expandable anchor also includes a distal end portion for exerting a radially outward force on the other of the first and second body vessels. (Specification page 17, lines 20-22).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants request review of the following outstanding grounds of rejection:

A) The rejection of Claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21, and 44 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 6,176,864 to Chapman ("Chapman");

B) The rejection of Claims 3 and 19 under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of U.S. Patent No. 2,898,913 to Ritter et al. ("Ritter");

C) The rejection of Claims 5, 13, 14, 18 and 25 under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of U.S. Patent No. 5,411,520 to Nash et al. ("Nash");

D) The rejection of Claims 7 and 22-24 under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of U.S. Patent No. 6,241,743 to Levin et al. ("Levin"); and

E) The rejection of Claim 10 under 35 U.S.C. §102(b) as being anticipated by Chapman, and the rejection of claim 10 under 35 U.S.C. §103(a) as being unpatentable over Chapman.

VII. ARGUMENTS

A) Claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21, and 44 are patentable under 35 U.S.C. §102(b) over U.S. Patent 6,176,864 to Chapman

Claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21, and 44 stand rejected under 35 U.S.C. §102(b) as being unpatentable over U.S. Patent 6,176,864 to Chapman.

Independent claim 1 of Appellant's disclosure recites a device for joining a first body vessel to a second body vessel comprising, *inter alia*, an expandable anchor having a "sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in [an] expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition."

Appellant respectfully submits that that independent claim 1, and dependent claims 2, 4, 6, 8, 9, and 12, are patentable over Chapman because the claimed subject matter is not anticipated by the subject matter of Chapman.

According to §2131 of the MPEP, to anticipate a claim, the reference must teach each and every element of the claim. Specifically, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

The Examiner has failed to show how the prior art, namely Chapman, teaches all of the limitations of Appellant's independent claim 1. Particularly, Chapman fails to disclose a sheath defining the shape of an expandable anchor when in an expanded condition such that a distal end

portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition. In fact, Chapman simply fails to provide any teaching or disclosure of an expandable anchor having an expanded condition in which a distal end portion is radially larger than a proximal end portion.

As described in Appellant's specification concerning one embodiment illustrated in Figure 13, "the shape and configuration of anchor 214, in the expanded condition, is substantially bell-shaped or fluted," (paragraph [0084]).

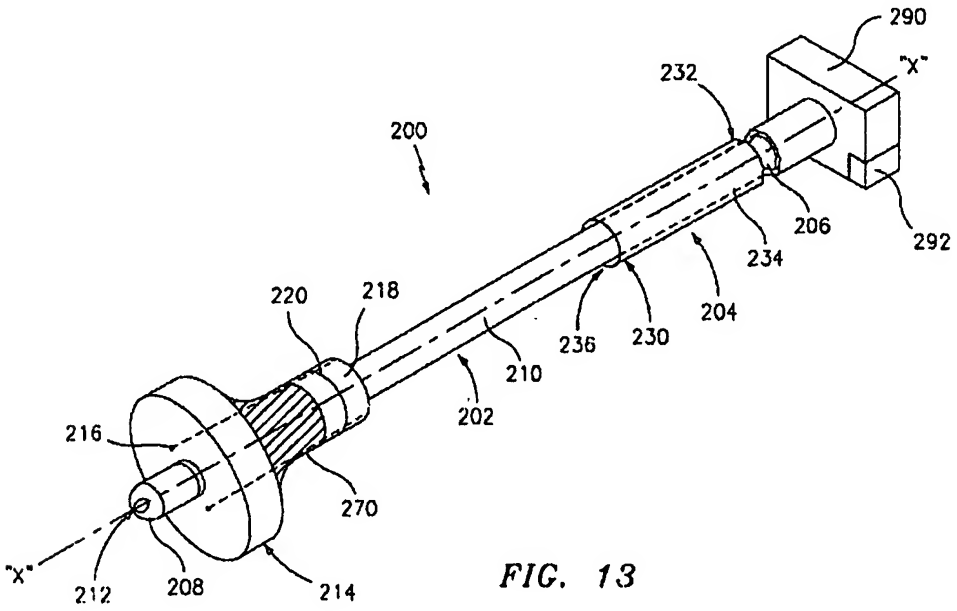


FIG. 13

As supported in the specification and recited in claim 1, the distal end portion of the expandable anchor is radially larger than the proximal end portion. Conversely, the graft coupling member 30 of Chapman is "radially compressible," and as defined in the specification of Chapman by 'radially compressible' it is meant that the graft coupling member 30 is generally

uniformly radially transformable between a free, normal expanded state and one or more compressed states.. ." (column 5, lines 38-40). The graft coupling member 30 is compressible so that it can be inserted into the introducer 40. Furthermore, nothing in Chapman suggests that the graft vessel 10, with the introducer 40 overlying the graft coupling member 30, could define the shape of the graft coupling member 30. Chapman does not disclose or suggest a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition, as recited in claim 1.

In contrast, Chapman discloses an anastomosis device for connecting a graft vessel 10 to a target vessel 12 as depicted in FIGS. 8 and 9 below. The graft vessel 10 is inserted through an opening in tubular member 20 (see col. 6, lines 38-45), and then a free end of the graft vessel is everted over an introducer 40 (see col. 6, lines 55-57). A graft coupling member 30 is compressed between the tubular member 20 and introducer 40 such that removing the introducer 40 permits the graft coupling member 30 to move to an expanded state (FIG 9). In the expanded state, the graft coupling member 30 is uniformly expanded within the everted end of the graft vessel 10 to "apply a gentle circumferentially uniform, radial pressure against the inverted graft vessel 10 and the inner wall of the target vessel 12" (col. 7, lines 47-50).

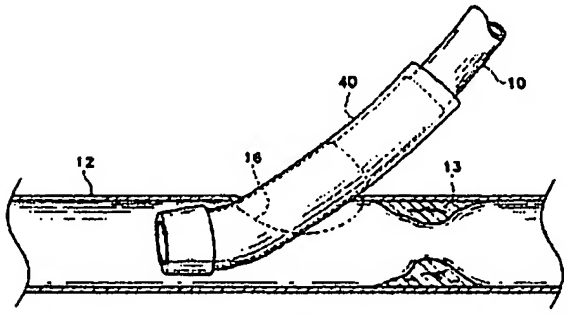


Fig. 8

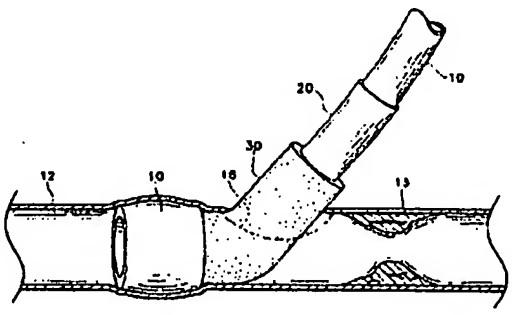


Fig. 9

In the Final Office Action, the Examiner asserts that the everted portion of graft member 10 defines the shape of graft coupling member 30 such that a distal end of the coupling member 30 is radially larger than a proximal end portion of the coupling member 30 when the coupling member 30 is in the expanded condition of FIG. 9.

The Examiner is incorrect about the disclosure of Chapman because the graft coupling member 30 in the expanded condition of FIG. 9 is radially uniform in diameter. A distal end of the coupling member 30 is *not* radially larger than a proximal end portion of the coupling member 30, as the asserted by the Examiner. In FIG. 9, the end of the graft that is expanded is the graft vessel 10 that has been everted over the graft coupling member 30. The graft coupling member 30 of Chapman is characterized as "radially compressible," which is defined at col. 5, lines 39-43 to mean "that the graft coupling member 30 is generally uniformly radially transformable" between expanded and compressed states. The uniform diameter of the coupling member 30 in the expanded condition permits the coupling member 30 to apply the gentle, "circumferentially uniform" radial pressure to the vessels 10 and 12 as indicated above.

In FIG. 9 of Chapman, the everted end of vessel 10 appears radially larger the coupling member 30. However, no portion of the coupling member 30 is radially larger than any other portion of the coupling member 30. Furthermore, the disclosure of Chapman stresses the uniform expansion of the coupling member 30. All this belies the Examiner's argument.

In the Advisory Action, the Examiner asserts that since the everted portion of graft member 10 covers a portion of the coupling member 30 in an expanded condition, the shape of

the coupling member 30 is defined by the everted portion of the graft member 10. The Advisory Action further states that "claim 1 does not clearly specify how the shape is defined."

The Examiner's assertion that "claim 1 does not clearly specify how the shape is defined" is wholly inconsistent with the recitation in claim 1 that "a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor." The Examiner seems to be indicating that the manner in which the sheath defines the shape of the anchor is not specified in claim 1. However, since a shape of an anchor is clearly defined in claim 1, and since Chapman fails to disclose this shape, Appellant believes that the coupling member 30 of Chapman is inconsistent with the requisite shape of the anchor recited in Claim 1

Therefore, Appellant respectfully submits that Chapman fails to anticipate each and every element of Claim 1, in that Chapman fails to disclose or suggest an expandable anchor in an expanded condition in which a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition.

Accordingly, since Chapman does not disclose or suggest each and every element of Claim 1, Appellant respectfully submits that the rejection of Claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Chapman should be reversed.

Since Claims 2, 4, 6, 8, 9, and 12 depend, directly or indirectly, from Claim 1 and contain all of the limitations of Claim 1, Appellant respectfully submits that Claims 2, 4, 6, 8, 9, and 12 are also not anticipated under 35 U.S.C. §102(b) over Chapman.

Independent Claim 15 recites a device for performing a surgical anastomosis of a first body vessel and a second body vessel, comprising, *inter alia*, a radially expandable anchor operatively disposable between the distal end portions of the pair of concentric tubular sleeves, the radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels.

Appellant respectfully submits that that independent Claim 15, and dependent Claims 16-17, 20, 21 and 44, are patentable over Chapman because the claimed subject matter is not anticipated by the subject matter of Chapman

The Examiner has failed to show how the prior art, namely Chapman, teaches all of the limitations of Appellant's independent Claim 15. Particularly, Chapman fails to disclose a radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels, as recited in independent Claim 15.

In one embodiment of the present application, as seen in FIG. 11 reproduced below, a proximal end portion 114b of expandable anchor 114 extends into the urethra "U" and exerts a radially outward force thereupon (see paragraph [0072]).

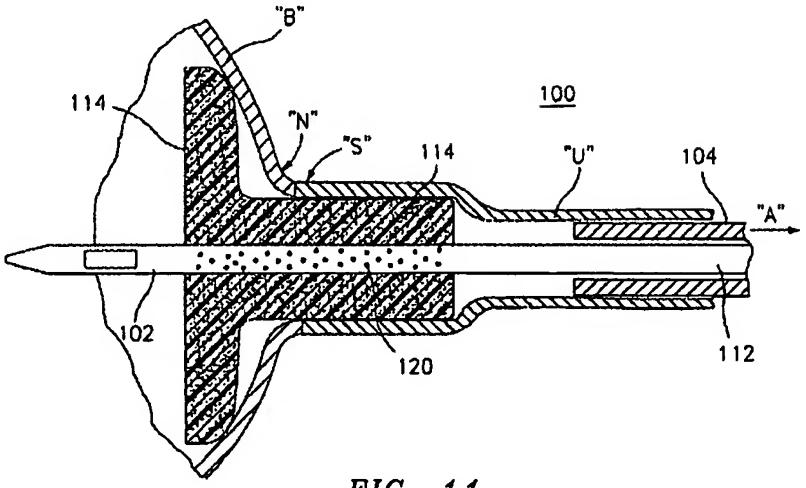


FIG. 11

In contrast to claim 15, the proximal end of the graft coupling member 30 of Chapman extends out of the target vessel 12 and radially surrounds the graft vessel 10. Only the distal portion of the coupling member arguably exerts a radially outward force on the graft vessel 10. Nothing in Chapman suggests the radially outward forces being exerted by the graft coupling member 30 that are required by claim 15. Furthermore, claim 15 requires the expandable anchor to engage a first and a second body vessel. Chapman does not teach or disclose this, as the proximal end of the coupling member does not exert a radially outward force on the vessel 12. Instead, the vessels 10 and 12 are coupled to one another at the distal end, as shown in FIG. 9.

As discussed hereinabove with regard to Claim 1, Chapman discloses a graft coupling member 30 that may be compressed between a tubular member 20 and an introducer 40. As indicated in FIG. 6 below, the introducer 40 extends into the everted end of graft vessel 10. The introducer 40 maintains the coupling member 30 in a compressed state as described at col. 6

lines 53-57. In the compressed state, the coupling member 30 does not exert a radially outward force on the graft vessel 10.

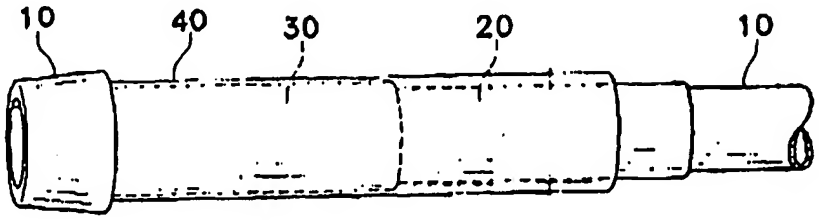


Fig. 6

The coupling member 30 exerts a uniform radial pressure on the inverted end of graft vessel 10 and the inner wall of target vessel 12 as discussed at col. 7, lines 47-49 with reference to FIG. 9 reproduced above. This radial pressure is exerted on the vessels 10 and 12 only because the introducer 40 has been removed. The radial pressure is exerted on the vessel 10 and vessel 12 at the same location, not on one vessel at a distal end of the anchor and on the other vessel at the proximal end of the anchor.

In the Final Office Action, the Examiner takes the position that since the coupling member 30 of Chapman expands along its length, the proximal and distal portion of the coupling member 30 are operative to provide a radially outward force. The Examiner notes that an intended use of a claimed device must result in a structural difference between the claimed device and the prior art in order to patentably distinguish the claimed device, and that if a prior art structure is capable of performing the intended use, then the claim is met. But Chapman simply does not disclose a radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body

vessels and a distal end portion for exerting a radially outward force *on the other* of the first and second body vessels

Therefore, Appellant respectfully submits that Chapman fails to anticipate each and every element of Claim 15, in that Chapman fails to disclose or suggest a radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels.

Accordingly, since Chapman does not disclose or suggest each and every element of Claim 15, Appellant respectfully submits that the rejection of Claim 15 as being anticipated under 35 U.S.C. §102(b) in view of Chapman should be reversed.

Since Claims 15-17, 20, 21, and 44 depend, directly or indirectly, from Claim 15 and contain all of the limitations of Claim 15, Appellant respectfully submits that Claims 15-17, 20, 21, and 44 are also not anticipated under 35 U.S.C. §102(b) over Chapman.

In view of the foregoing, the rejection of Claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21, and 44 as being anticipated under 35 U.S.C. §102(b) over Chapman has not been established because the Examiner has failed to show how the prior art references teach or suggest all of the limitations of Appellant's Claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21, and 44. Therefore, Appellant respectfully submits that a *prima facie* case of anticipation has not been established and the rejection of Claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21, and 44 under 35 U.S.C. §102(b) should be reversed.

B) Claims 3 and 19 are patentable under 35 U.S.C. §103(a) over Chapman in view of U.S. Patent 2,898,913 to Ritter et al.

Claims 3 and 19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of U.S. Patent 2,898,913 to Ritter et al. ("Ritter"). Claims 3 and 19 of Appellant's disclosure recite, *inter alia*, an expandable anchor having a frusto-conical shape when in an expanded condition.

Appellants respectfully submit that that Claims 3 and 19 are patentable over Chapman in view of Ritter because the claimed subject matter is not obvious over the subject matter of Chapman in view of Ritter.

According to § 2143.03 of the MPEP, in order "to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." The Examiner has failed to show how the prior art, namely Chapman in view of Ritter, teaches or suggests all of the limitations of Appellant's Claims 3 and 19.

For example, in regards to Claim 3, Chapman fails to disclose a sheath defining the shape of an expandable anchor when in an expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition as discussed above with reference to independent Claim 1. In regards to Claim 19, Chapman fails to disclose a a radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels, as discussed above with reference to independent Claim 15.

Appellant respectfully submits that Ritter fails to remedy the deficiencies of Chapman with regard to Claims 3 and 19. In the Final Office Action, the Examiner relies on Ritter for the disclosure of an anchor having a frusto-conical shape. Ritter relates generally to a hemostatic cone for insertion into the fossal cavity to enhance the healing process following a prostatectomy (see col. 1, lines 15-20).

Appellant submits that even if Ritter does disclose an anchor having a frusto-conical shape, Ritter fails to cure the deficiencies of Chapman in that Ritter does not disclose "a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition" as recited in independent Claim 1. Also, Ritter does not disclose a "radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels," as recited in independent Claim 15.

Accordingly, in view of the foregoing, since Ritter fails to cure the deficiencies of Chapman, Appellant submits that Claims 3 and 19 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Ritter. The rejection of Claims 3 and 19 under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of Ritter has not been established because the Examiner has failed to show how the prior art references teach or suggest all of the limitations of Appellant's Claims 3 and 19. Therefore, Appellant respectfully submits that a *prima facie* case of obviousness has not been established and the rejection of Claims 3 and 19 under 35 U.S.C. §103(a) should be reversed.

C) Claims 5, 13, 14, 18 and 25 are patentable under 35 U.S.C. §103(a) over Chapman in view of U.S. Patent No. 5,411,871 to Nash et al.

Claims 5, 13, 14, 18 and 25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of U.S. Patent No. 5,411,871 to Nash et al. ("Nash").

For at least the reasons presented above regarding the patentability of independent Claims 1 and 15 under 35 U.S.C. §102(b) as being patentable over Chapman, the subject matter of Claims 5, 13, 14, which depend from independent Claim 1, and the subject matter of Claims 18 and 25, which depend from independent Claim 15, as a whole are also patentably distinguishable over Chapman.

In addition to depending from independent Claims 1 and 15, Claims 5, 13, 14, 18 and 25 are also allowable over Chapman in view of Nash because Nash fails to cure the deficiencies of Chapman. In particular, Chapman does not disclose a sheath defining the shape of an expandable anchor when in an expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition as recited in independent Claim 1, Also Chapman does not disclose a radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels, as recited in independent Claim 15.

In the Final Office Action, the Examiner relied on Nash for the disclosure of a plug that expands upon contact with moisture. Nash relates generally to a system for sealing a

percutaneous puncture in a blood vessel and discloses a collagen plug 30 that expands in the presence of blood (see col. 7, lines 1-4). Appellant submits that even if Nash does disclose a plug that expands upon contact with moisture, Nash fails to cure the deficiencies of Chapman in that Nash does not disclose "a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition" as recited in independent Claim 1. Also, Nash does not disclose a "radially expandable anchor including a proximal end portion "configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels," as recited in independent Claim 15.

Accordingly, in view of the foregoing, since Nash fails to cure the deficiencies of Chapman, Appellant submits that Claims 5, 13, 14, 18 and 25 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Nash. The rejection of Claims 5, 13, 14, 18 and 25 under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of Nash has not been established because the Examiner has failed to show how the prior art references teach or suggest all of the limitations of Appellant's Claims 5, 13, 14, 18 and 25. Therefore, Appellant respectfully submits that a *prima facie* case of obviousness has not been established and the rejection of Claims 5, 13, 14, 18 and 25 under 35 U.S.C. §103(a) should be reversed.

D) Claims 7 and 22-24 are patentable under 35 U.S.C. §103(a) over Chapman in view of U.S. Patent No. 6,241,743 to Levin et al.

Claims 7 and 22-24 are stand rejected under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of U.S. Patent No. 6,241,743 to Levin et al. ("Levin").

For at least the reasons presented above regarding the patentability of independent Claims 1 and 15 under 35 U.S.C. §102(b) as being patentable over Chapman, the subject matter of Claim 7, which depends from independent Claim 1, and the subject matter of Claims 22-24, which depend from independent Claim 15, as a whole are also patentably distinguishable over Chapman.

In addition to depending from independent Claims 1 and 15, Claims 7 and 22-24 are also allowable over Chapman in view of Levin because Levin fails to cure the deficiencies of Chapman. In particular, Chapman does not disclose a sheath defining the shape of an expandable anchor when in an expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition as recited in independent Claim 1, Also Chapman does not disclose a radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels, as recited in independent Claim 15.

In the Final Office Action, the Examiner relied on Levin for the disclosure of an anastomosis device defining a porous structure. Levin relates generally to a device for creating

an end to side anastomosis having a generally tubular structural member 12 (see col. 4, line 64) with a porous region 26 (see col. 5, lines 63-67). Appellant submits that even if Levin does disclose a tubular member with a porous region, Levin fails to cure the deficiencies of Chapman in that Levin does not disclose "a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition" as recited in independent Claim 1. Levin also fails to disclose a radially expandable anchor including a proximal end portion "configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels," as recited in independent Claim 15.

Accordingly, in view of the foregoing, since Levin fails to cure the deficiencies of Chapman, Appellant submits that Claims 7 and 22-24 are allowable under 35 U.S.C. § 103(a) over Chapman in view of Levin. The rejection of Claims 7 and 22-24 under 35 U.S.C. §103(a) as being unpatentable over Chapman in view of Levin has not been established because the Examiner has failed to show how the prior art references teach or suggest all of the limitations of Appellant's Claims 7 and 22-24. Therefore, Appellant respectfully submits that a *prima facie* case of obviousness has not been established and the rejection of Claims 7 and 22-24 under 35 U.S.C. §103(a) should be reversed.

E) Claim 10 is patentable under 35 U.S.C. §102(b) over Chapman and under 35 U.S.C. §103(a) over Chapman.

Claim 10 stands rejected under 35 U.S.C. §102(b) as being anticipated by Chapman, or in the alternative under 35 U.S.C. §103(a) as being unpatentable over Chapman.

For at least the reasons presented above regarding the patentability of independent Claim 1 under 35 U.S.C. §102(b) as being patentable over Chapman, the subject matter of Claim 10, which depends from independent Claim 1, as a whole is also patentably distinguishable over Chapman.

Accordingly, Appellant submits that Claim 10 is allowable under 35 U.S.C. §102(b) over Chapman and under 35 U.S.C. § 103(a) over Chapman. The rejection of Claim 10 has not been established because the Examiner has failed to show how the prior art references teach or suggest all of the limitations of Appellant's Claims 10. Therefore, Appellant respectfully submits that a *prima facie* case of neither anticipation nor obviousness has not been established and the rejection of Claim 10 under 35 U.S.C. §102(b) and 35 U.S.C. §103(a) should be reversed.

VIII. CONCLUSION

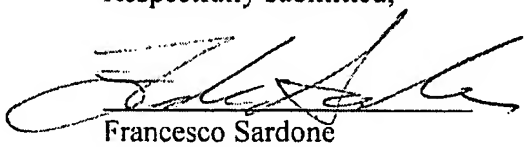
In view of the foregoing remarks, Appellants respectfully submit that all of the claims now pending in this application, namely, Claims 1-10, 12-25, and 44 are in condition for allowance. Early and favorable reconsideration of this application is respectfully requested.

Please charge any deficiency as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any

overpayment of such fee(s) to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required and charge Deposit Account No. 21-0550 therefore.

An early and favorable response on the merits is earnestly requested.

Respectfully submitted,



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IX. CLAIMS APPENDIX

Claim 1. (Rejected) A device for joining a first body vessel to a second body vessel, comprising:

an inner member having a distal end portion and defining a longitudinal axis;

an outer member defining a lumen dimensioned to receive the inner member therein;

a radially expandable anchor disposed at the distal end of the inner member, the expandable anchor having an initial condition wherein the expandable anchor is disposed between the outer member and the inner member and an expanded condition; and

a sheath disposed about the expandable anchor for defining the shape of the expandable anchor when in the expanded condition such that a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition.

Claim 2. (Rejected) The device according to claim 1, wherein the expandable anchor is made from at least one of a sponge-like and a foam-like material.

Claim 3. (Rejected) The device according to claim 2, wherein the expandable anchor has a frusto-conical shape when in the expanded condition.

Claim 4. (Rejected) The device according to claim 3, wherein a distal end portion of the expandable anchor is radially larger than a proximal end portion of the expandable anchor when in the expanded condition.

Claim 5. (Rejected) The device according to claim 2, wherein the expandable anchor radially expands upon contact with moisture.

Claim 6. (Rejected) The device according to claim 1, wherein the inner member comprises an inner tubular sleeve defining a central lumen extending therethrough.

Claim 7. (Rejected) The device according to claim 6, wherein the inner tubular sleeve includes a region near its distal end which is porous to permit transmission of moisture, via the central lumen, to the expandable anchor.

Claim 8. (Rejected) The device according to claim 6, wherein the expandable anchor is arranged, when in the expanded condition, to permit liquid to pass therethrough and drain through the inner tubular sleeve.

Claim 9. (Rejected) The device according to claim 1, wherein the expandable anchor defines at least one longitudinally oriented passage extending completely therethrough when in the expanded condition.

Claim 10. (Rejected) The device according to claim 1, further comprising a control unit, remotely located, for operating the anastomotic device.

Claim 11. (Cancelled).

Claim 12. (Rejected) The device according to claim 1, further comprising a grasper operatively connected to the distal end of the inner tubular sleeve.

Claim 13. (Rejected) The device according to claim 2, wherein the expandable anchor is fabricated from a bio-absorbable material.

Claim 14. (Rejected) The device according to claim 13, wherein the material dissolves after a predetermined period of time.

Claim 15. (Rejected) A device for performing a surgical anastomosis of a first body vessel and a second body vessel, comprising:

a pair of concentric tubular sleeves including an outer sleeve and an inner sleeve, each of the pair of concentric tubular sleeves having a distal end portion and a proximal end portion; and

a radially expandable anchor operatively disposable between the distal end portions of the pair of concentric tubular sleeves, the radially expandable anchor including a proximal end portion configured for exerting a radially outward force on at least one of the first and second body vessels and a distal end portion for exerting a radially outward force on the other of the first and second body vessels.

Claim 16. (Rejected) The device according to claim 15, wherein the expandable anchor is fabricated from at least one of a foam-like and sponge-like material.

Claim 17. (Rejected) The device according to claim 16, wherein the expandable anchor has an initial condition for insertion of the anastomotic device through a body lumen and an expanded condition which inhibits withdrawal of the anastomotic device from the body lumen.

Claim 18. (Rejected) The device according to claim 17, wherein the expandable anchor is expanded from the initial condition to the expanded condition by application of a fluid.

Claim 19. (Rejected) The device according to claim 17, wherein the expandable anchor has a frusto-conical shape when in the expanded condition.

Claim 20. (Rejected) The device according to claim 17, wherein the expandable anchor has a thin-walled cylindrical shape when in the initial condition.

Claim 21. (Rejected) The device according to claim 17, wherein the expandable anchor defines at least one longitudinally oriented passage extending entirely therethrough when in the expanded condition.

Claim 22. (Rejected) The device according to claim 17, wherein the inner tubular sleeve of the pair of concentric tubular sleeves includes a region of porosity formed near the distal end thereof.

Claim 23. (Rejected) The device according to claim 22, wherein the region of porosity to transmit a fluid to the expandable anchor.

Claim 24. (Rejected) The device according to claim 23, wherein the inner tubular sleeve includes at least one longitudinally oriented lumen extending therethrough, wherein the lumen is configured and adapted to transmit the fluid to the plurality of perforations.

Claim 25. (Rejected) The device according to claim 16, wherein the expandable anchor is fabricated from a bio-absorbable material.

Claim 26. (Withdrawn) A method of performing a surgical anastomosis, comprising the steps of:

providing a device for performing the surgical anastomosis, the device including:

a member having a distal end portion;

a radially expandable anchor operatively disposed at the distal end portion of the member; and

a cover disposed over the radially expandable anchor; and

passing the device through an opening in a first body vessel and into a second body

vessel such that a distal end portion of the expandable anchor is positioned at least partially within the second body vessel;

withdrawing the cover to expose at least the distal end portion of expandable anchor;

expanding at least the distal end portion of the expandable anchor within the second body vessel such that the expandable anchor engages the second body vessel;

moving the device until the second body vessel contacts a distal end of the first body vessel and a proximal end portion of the expandable anchor is positioned at least partially within the distal end of the fist body vessel;

withdrawing the cover to expose the proximal end portion of the expandable anchor; and

expanding the proximal end portion of the expandable anchor within the distal end of the first body vessel such that the expandable anchor engages the distal end of the first body vessel.

Claim 27. (Withdrawn) The method according to claim 26, wherein the steps of expanding include the introduction of a fluid to the expandable anchor.

Claim 28. (Withdrawn) The method according to claim 26, wherein the expandable anchor is fabricated from at least one of a foam-like and sponge-like material.

Claim 29. (Withdrawn) The method according to claim 28, wherein the expandable anchor is expanded by application of liquid thereto.

Claim 30. (Withdrawn) The method according to claim 29, wherein the expandable anchor has a frusto-conical shape when in an expanded condition.

Claim 31. (Withdrawn) The method according to claim 29, wherein the expandable anchor has a thin-walled cylindrical shape when in a compressed condition.

Claim 32. (Withdrawn) The method according to claim 29, wherein the member comprises an inner tubular sleeve having a region of porosity formed near the distal end thereof and the liquid is introduced through the sleeve, through the region of porosity, to the expandable anchor.

Claim 33. (Withdrawn) The method according to claim 26, wherein the step of moving comprises approximating a body organ and a body lumen.

Claim 34. (Withdrawn) An anchoring device, comprising:

a member having a distal end;

a radially expandable anchor disposed at the distal end of the member; and

a cover disposed over the radially expandable anchor to maintain the radially expandable member in an initial pre-expanded condition.

Claim 35. (Withdrawn) The anchoring device of claim 34, wherein the cover comprises a tubular sleeve having a lumen sized to receive the member and the radially expandable anchor.

Claim 36. (Withdrawn) The anchoring device of claim 34, wherein the radially expandable anchor is sized so that upon removal of the cover, the anchor expands.

Claim 37. (Withdrawn) The anchoring device of claim 34, wherein the radially expandable anchor comprises a sponge that radially expands upon the introduction of a fluid.

Claim 38. (Withdrawn) A method of deploying an anchoring device, comprising:

providing an expandable anchor, the expandable anchor being expandable upon introduction of a fluid;

introducing the fluid to a first portion of the expandable anchor so that the first portion is expanded and a second portion of the expandable anchor remains in the pre-expanded configuration; and

introducing the fluid to the second portion of the expandable anchor so that the second portion is expanded.

Claim 39. (Withdrawn) The method of claim 38, wherein the expandable anchor comprises a sponge and the fluid comprises a liquid.

Claim 40. (Withdrawn) The method of claim 38, wherein the expandable anchor comprises a membrane expanded upon introduction of the fluid.

Claim 41. (Withdrawn) The method of claim 38, wherein the first portion engages a body vessel upon expansion.

Claim 42. (Withdrawn) The method of claim 41, further comprising the step of moving the expandable anchor, after the first portion is expanded, so that a second body vessel is adjacent the second portion.

Claim 43. (Withdrawn) The method of claim 42, wherein the second portion engages the second body vessel upon expansion.

Claim 44. (Rejected) The device according to claim 15, wherein the radially expandable anchor is configured for exerting a radially outward force on an inner surface of the first and second body vessels along substantially the entire length of the radially expandable anchor.

X. EVIDENCE APPENDIX

None

XI. RELATED PROCEEDINGS APPENDIX

None